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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/610,935	07/06/2000	Brian W. Ward	SGM 6934.1	5148

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SENNIGER POWERS LEAVITT AND ROEDEL
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EXAMINER

SISSON, BRADLEY L

ART UNIT PAPER NUMBER

1634

DATE MAILED: 09/11/2002

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/610,935

Applicant(s)

WARD ET AL.

Examiner

Bradley L. Sisson

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11,13-16 and 20-33 is/are pending in the application.
- 4a) Of the above claim(s) 23-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11,13-16 and 20-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Location of Application

1. The location of the subject application has changed. The subject application is now located in Group 1630, Art Unit 1634.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 01 August 2002 has been entered.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 11, 13-16, and 20-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

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application was filed, had possession of the claimed invention. As presently worded, the composition of claim 1 must comprise a thermostable DNA polymerase and an anionic tracer dye, be substantially free of template and have an optical density greater than about 5 at a visible wavelength of maximal tracer absorbance. A review of the specification fails to find such a composition being described in such full and concise terms as to reasonably suggest that applicant was in possession of such a composition at the time of filing.

5. In Table 1 applicant identifies over 180 red dyes that were evaluated. Table 2 lists 40 anionic dyes that were selected for further study. Upon review of Table 2, only four dyes, Acid Red 4, Acid Red 1, Amaranth, and Acid Violet 5 were found to be suitable. While the specification suggests that other colored dyes may be useful in the claimed composition, the specification has not been found to provide an adequate written description of these dyes.

6. A review of the specification fails to find where any composition has been formulated with any of these four dyes such that it would have "an optical density greater than about 5 at a visible wavelength of maximal tracer absorbance," would also have a density of "at least about 1.01 g/cm³" or "at least about 1.1 g/cm³." As presently worded, the density encompasses values ranging up to infinity. Clearly, the specification has not provided an adequate written description of such a composition.

7. While claims 20-22 add further limitations in that the polymerase is *Taq* polymerase, and that Acid Red 1 and Acid Violet 5 are to be used, the specification does not set forth a range of formulations that have the requisite optical densities at a visible wavelength nor does the specification set forth an adequate written description of a range of formulations that would also satisfy the required open-ended range of density (g/cm³).

8. At page 3, bridging to page 4 of the response received 01 August 2002, attention is directed to where the specification provides support for polymerase, and certain dyes and to Example 1 where a composition comprising Taq polymerase, Acid Red 1 and Acid Violet 5 is presented. It is asserted that this showing satisfies the written description requirement.

9. The above argument has been fully considered and has not been found persuasive towards the withdrawal of the rejection. While agreement is reached in that a composition comprising Taq, Acid Red 1 and Acid Violet 5 has been described, the specification does not describe a formulation having the requisite optical density and specific gravity. It is further noted that the invention of claims 11 and 13-16 is not limited to Taq polymerase nor is it limited to the two above-identified anionic tracer dyes.

10. At pages 4-6 of the response it is asserted that it would be obvious to one of skill in the art to arrive at other and obvious variations of the disclosed compositions due to similarities in structure, mechanism of action, etc., of the polymerase. It is further asserted, with reference to the Declaration of Brian W. Ward under 37 CFR 1.132, that one of skill in the art would assume that possession of one thermostable polymerase would constitute possession of all thermostable DNA polymerases.

11. The above argument has been fully considered and has not been found persuasive towards the withdrawal of the rejection. It is noted with particularity that the claims are not drawn to a DNA polymerase per se, but to a composition that comprises same. The claims require that a thermostable DNA polymerase be combined with an anionic tracer dye whereby the composition has an optical density "greater than about 5 at a visible wavelength of maximal tracer absorbance." As set forth above, the specification has not been found to provide an

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adequate written description of this composition so as to reasonably suggest that applicant was in possession of the full genus of such compositions which comprised not only these two components but conceivably comprises virtually any other compound or composition. While one may well argue that one of skill in the art at the time would have found it obvious to substitute one polymerase or tracer dye for that of another, obviousness is not dispositive of the issue of written description. Rather, one looks to the specification to see what, if anything, the disclosure reasonably suggests that applicant was in possession of at the time of filing. It is well settled that "[I]t is not enough for purposes of written description requirement of Section 112 that the disclosure, when combined with the knowledge in the art, would lead one to speculate as to modification that the inventor might have envisioned, but failed to disclose." *Lockwood v.*

American Airlines Inc. (Fed. Cir. March 1997) 41 USPQ2d 1961 at 1966.

12. At page 5 of the response argument is presented that the specification exemplifies 6 dyes that work with Taq polymerase. It is noted at page 25 of the specification that those dyes that have a mark in the various columns were removed, not retained, from the study. Accordingly, only 4, not 6 dyes were found to be satisfactory out of the 215 that were originally evaluated.

13. Agreement is reached in that applicant need not exemplify each and every embodiment encompassed by the claims. It is well settled, however, that the disclosure must set forth a sufficient number of examples so to reasonably suggest that applicant was in possession of the invention at the time of filing. A review of the disclosure, and even applicant's response directs attention to the aspect that only red dyes were evaluated. Clearly, if but one color of dye was evaluated, then the disclosure quite clearly articulates that applicant did not evaluate, much less have in possession any other type of dye. Obviousness of substitution, or a finding of aesthetic

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pleasure does not translate into the disclosure reasonably suggesting that applicant was in possession of any other suitable dye.

14. Accordingly, and in the absence of convincing evidence to the contrary, the specification has not been found to satisfy the written description requirements of 35 USC 112, first paragraph.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

18. Claims 11, 13-16, and 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Köster et al. (US Patent 5,928,906), in view of Nardone et al. (US Patent 6,117,986).

19. Köster et al., column 12, disclose a variety of compositions that comprise a tracer dye, and a thermostable DNA polymerase (Taq polymerase). It is noted with particularity that Köster et al., states that the template is added to this mixture.

20. The dyes described by Köster et al., are not defined in terms of their being anionic tracer dye, nor are they Acid red 1 or Acid Violet 5.

21. Nardone, et al., column 6 that Acid Red 1 and Acid Violet 5 were used to label or trace nucleic acids.

22. It would have been obvious to one of ordinary skill in the art at the time that the invention was made to have used anionic dyes such as Acid red 1 and Acid Violet 5 in the composition of Köster et al., as these anionic tracer dyes were known in the art to enhance nucleic acid assays.

In view of the well-developed nature of the art, and the explicit guidance found therein, the ordinary artisan would have been highly motivated and would have had a most reasonable expectation of success.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978.

The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
September 3, 2002